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### **REMARKS**

The Applicants will address the Examiners' rejections in the order presented in the office action.

#### **Election/Restriction**

Applicants confirm the telephonic election of claims 1, 28-36, or those claims in Group I. Applicants reserve the right to pursue divisional patent filings to claims in Groups II and/or III. The Examiner will note that Applicants have cancelled non-elected claims, 2-27.

#### **Double Patenting**

Claim 1 stands provisionally rejected under 35 U.S.C. §101 as claiming the same invention as that of claim 1 of co-pending Application No. 10/303,598, and of claim 1 of co-pending Application No. 09/714, 409. Applicants believe that claim 1 as now amended obviates the provisional double patenting rejection.

#### **Claim Rejections-35 USC § 112, 1<sup>st</sup> paragraph**

The Examiner has stated that:

"Claims 1, and 28-36 stand rejected under 112, 1<sup>st</sup> paragraph because the specification...does not reasonably provide enablement for all other virus vectors comprising an E2F responsive promoter operably linked to any viral gene, and a method of killing tumor cells in vivo using said virus vector."

The Examiner has also stated that the specification is enabled:

"...for an adenovirus vector comprising the E2F responsive promoter operably linked to an adenovirus immediate early gene and further comprising viral packaging repeat sequences..."

In this light, the Examiner will note, that Applicants have amended claim 1 to recite that the virus vector is "adenovirus," and, further, that the E2F responsive transcriptional nucleotide

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regulatory site controls the expression of "an early adenoviral gene." Also, Applicants have additionally amended claim 1 to recite that adenoviral packaging sequences differ in their number, or position when compared to Onyx 411. Support for this language is set forth in Example 9 of Applicants' specification.

The Examiner will note that the rejection as to claims 28 and 29 is moot as these claims have been cancelled.

Thus, it is respectfully submitted that the 112 1<sup>st</sup> paragraph rejection should be withdrawn in light of the stated amendments to the claims.

#### **Claim Rejections-35 USC 102**

Claims 1 and 28-29 stand rejected under 102(b) as being anticipated by Parr et al. (1997, Nature Medicine, Vol. 3, pgs. 1145-1149). The rejection as to claims 28 and 29 is moot as these claims have been cancelled.

The Examiner will note that as amended claim 1 recites an E2F responsive transcriptional nucleotide regulatory site that controls the expression of an *early adenoviral gene*. This is distinct from what is shown in Parr et al, which is an E2F1 promoter that controls the expression of the *herpes thymidine kinase gene*. Thus, Applicants respectfully submit that as amended claim 1 is not anticipated by Parr et al.

Claims 34-35 stand rejected under 102(b) as being anticipated by Schmid et al. (1997, J. Virology, vol. 71, pgs. 3375-3384). The Examiner will note that Applicants have cancelled these claims, and thus the rejection is moot.

#### **New Claims**

The Examiner's attention is drawn to newly added claims 37-41. Claims 37 and 38 claim a method for treating cancer using the invention adenoviral vectors. Claims 39-41 claim a method of making the adenoviral vectors. The Examiner will note that these claims cover aspects of Applicants' invention that are well described in their Application, particularly in Example 9.

#### **Conclusion**

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Applicants believe that they have addressed all the outstanding rejections, and earnestly solicit the Examiner to expedite allowance of the application.

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The Commissioner is authorized to charge any fees associated with this communication to Deposit Account No. 15-0615 and for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

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